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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,640	02/09/2007	Özlem Türeci	VOS-120	4630

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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,640	TÜRECI ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 19-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11 & 19-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-8, 11 and 31-38, drawn to a fusion protein comprising an antigen, a transmembrane region and a cytoplasmic region of a chain of an MHC molecule, and pharmaceutical composition thereof.

II. Claims 9, 10, 19, 20 and 39-41, drawn to a nucleic acid molecule encoding a fusion protein comprising an antigen, a transmembrane region and a cytoplasmic region of a chain of an MHC molecule, and a host cell that comprises a nucleic acid molecule, and pharmaceutical composition thereof.

III. Claims 21, 24 and 27-30, drawn to a method of inducing the formation of MHC/antigen peptide complexes in a cell, inducing an immune response to a specific antigen in a living organism, or a method of treating or immunizing a living organism suffering or at risk of developing a target disease, said comprising contacting the cell *with the fusion protein* of claim 1.

IV. Claim 22, drawn to a method for inducing the formation of MHC/antigen peptide complexes in a cell, said comprising contacting the cell *with at least one nucleic acid molecule* which encodes a fusion protein of claim 1.

V. Claim 23, drawn to a method for inducing the formation of MHC/antigen peptide complexes in a cell, the method comprising contacting the cell with at least one host cell of claim 10.

VI. Claim 25, drawn to a method of activating T cells toward a specific antigen comprising contacting the T cells with APCs that have been previously treated with at

least one fusion protein of claim 1, wherein the antigen portion of the fusion protein comprises the specific antigen.

VII. Claim 26, drawn to a method of stimulating or activating T cells against a specific antigen, the method comprising contacting T cells with at least one fusion protein of claim 1, wherein the antigen portion of the fusion protein comprises the specific antigen. How is this different from group IV It's different because in this case the fusion protein is stimulating the T cells. In the other instance, the cells are incorporating the fusion protein into them, and those can be used as antigen presenting cells to stimulate T cells.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Rhode *et al* (J. Immunol. 1996, 157: 4885-4891). Rhode *et al* teach a MHC fusion protein which comprises an antigen peptide, a transmembrane region and a cytoplasmic region of a chain of said MHC molecule (especially Figure 1 and first paragraph at column 1 on page 4889. Note that instant claim 1 does not recite that the fusion protein is "isolated", and the open transitional phrase “comprising” renders the claim open to other non-recited components such as the alpha and beta chains of MHC as well as the signal peptide.

Therefore, the instant invention lacks Unity of Invention.

3. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

4. This application contains claims directed to or generic to the following patentably distinct species:

Of Inventions I, III, IV, VI and VII:

- A specific fusion protein, for example one that comprises SEQ ID NO: 14 OR SEQ ID NO: 12 (see claim 37). Applicant is further required to specify which SEQ ID NO correspond to the transmembrane and cytoplasmic regions (see claim 35) and which SEQ ID NO corresponds to the cytoplasmic region (see claim 36). Applicant is further required to specify which antigen is comprised in the construct, for example, the antigen is a tumor antigen that is CEA. Applicant is further required to elect which MHC the transmembrane and cytoplasmic regions are derived from, for example, MHC class I.

- In addition, if the Invention of Group III is elected, Applicant is required to specify if the method involves contacting cells with the fusion protein *in vitro* or involves administration of the fusion protein *in vivo*.

Of Inventions II and V:

- A specific nucleic acid molecule encoding a specific fusion protein, for example one that comprises SEQ ID NO: 13 OR SEQ ID NO: 11 (see claim 41). Applicant is further required to specify which SEQ ID NO correspond to nucleic acid sequence encoding the transmembrane and cytoplasmic regions (see claim 39) and which SEQ ID NO corresponds to nucleic acid sequence encoding the cytoplasmic region (see claim 40). Applicant is further required to specify which antigen is encoded in the construct, for example, the antigen is a tumor antigen that is CEA. Applicant is further required to elect which MHC the encoded transmembrane and cytoplasmic regions are derived from, for example, MHC class I.

The species are independent or distinct because they have different sequences. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: the different SEQ ID NO have different sequences that require different searches of either protein or nucleic acid databases.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should Applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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